

RESEARCH ARTICLE

Regulatory regime on Indian medical device industry – a way forward

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Medical devices are essential for safe and effective prevention, analysis, cure and rehabilitation of illness and disease. Till December, 2017 Medical Devices come under the Drugs and Cosmetics Act 1940, but after Indian Ministry of Health and Family Welfare released the new guidelines it comes under Medical Device Act. CDSCO launches online service for medical devices, diagnostics in Sugam portal which effective from 1st January 2018. This will help manufacturer to submit applications for grant of import, manufacture, clinical investigation, sale and distribution licenses of medical devices and diagnostics. In 2020, approved medical devices must bear unique identifiers. From January 1st 2022, medical devices that are approved for import, sale, or distribution in India must bear two different types of unique identifiers. In order to ensure safety and efficacy Government set up two dedicated medical device testing laboratories in the country at Vadodara in Gujarat and Noida in Uttar Pradesh. Such type of testing labs will allow manufacturers to overcome deficiencies in their products and improve product value in the market which is a neglected aspect until now.

Keywords: Medical Device, Orthopedic implants, NHSRC, Sugam Portal**INTRODUCTION**

‘**Medical device**’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of¹:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. Investigation, replacement, modification, or support of the anatomy or of a physiological process,
3. Supporting or sustaining life,
4. Control of conception

Healthcare has become one of India’s major economic sector both in terms of income and employment. India is full of opportunities for medical devices companies to explore and expand their business prospects in the ever-booming Indian healthcare market. The Indian medical devices market is currently valued at around \$10 billion and has been growing at an average rate of 15% for the past couple of years. As per the market evaluations, the industry is expected to reach close to \$25 billion by 2025. Indian medical

device industry comprises of over 800 Indian manufacturers of which close to 65% of companies have turnover of over Rupees 10 crore (\$1.5 million) and 2% companies with a turnover of more than Rupees 500 crore (\$73 million).²

Growth Factors Driving the Medical Device Demand in India

The various factors are driving the demand of medical device in India as mentioned below.

Growing Population

India had a population 1.21 billion in 2011 which is growing at a rate of 1.2 per cent per year and will reach 1.36 billion in 2021. The growing population will drive the demand for healthcare services and this in turn will drive the demand for medical devices in India.

Increasing Disease Burden of Chronic Diseases

Non-communicable diseases like cardio vascular diseases, cancer, diabetes, and other, are expected to comprise more than 75% of India’s disease burden by 2025, compared to 45% in 2010. The chronic diseases will drive the demand for

healthcare services with basic and advanced medical devices and technology.³

Demand for Healthcare Infrastructure

Currently, the healthcare delivery system has an acute shortage of availability of hospital infrastructure. India has an estimated 1.1 beds per 1,000 people, which is well behind the 3.5 beds per 1000 people recommended by the WHO. The healthcare delivery system will need additional 3.6 million beds to reach the recommended capacity. The demand for additional beds will drive the demand for medical devices. The government has announced a plan in July 2015 to have a medical college in every district. Additionally, five new AIIMS are proposed to be set up in J&K, Punjab, Tamil Nadu, Himachal Pradesh and Assam, and one AIIMS like institute to be set up in Bihar. This is significantly bound to increase the demand for medical devices, considering ~30% of the total project cost is constituted by medical devices.

Medical Device Rules 2017 GSR 78(E)

In January 2017, India's Ministry of Health and Family Welfare released the new Medical Device Rules, which effective from **January 1, 2018**. Till 2017 medical devices come under the Drugs and Cosmetics Act, but after implementing new rules, it comes under **Medical Device ACT**. New rules having well formalized registration requirements compared to the country's current system⁴.

The new rules adopt a risk-based classification scheme

All medical devices will be placed into one of **four classes**

Class A (low risk)

Class B (low moderate risk)

Class C (moderate high risk)

Class D (high risk)⁵

It is based on the intended use of the device and the potential risk that comes with its use. Each class has different regulatory processes. Now there will be strict regulation for getting approval.

- Licenses issued to device registrants would remain valid indefinitely, along with payment of license retention fees, unless cancelled or surrendered.
- The Rules include fee revisions based on device classification.
- According to new rule Test licenses will remain valid for **three years**; currently, it is valid for **one-year only**.

- Device manufacturing sites in India must undergo audits by Notified Bodies in order to obtain manufacturing licenses.
- The Medical Device Rules, 2017 includes an itemized list of costs that correlate to each stage of the application and registration process.
- Registration Certificates last for **five years**.
- The 2017 Rules has removed need of registration certificate for registration of a foreign manufacturer, its manufacturing site and the products. Currently they need to make two separate applications (registration and import license) to import and market products in India. After commencement of the Rules 2017, the foreign manufacturer needs to appoint an authorized agent in India and apply for an import license through it to import and market products in the country. The applicant will get import license in nine months.
- India's certificate renewal process is much less rigorous than that of other countries. To maintain the indefinite validity of the certificate, its holder must pay a registration retention fee of **20,000 rupees** (approximately \$310) every **five years** from the date of issue.⁶

Online applications for licenses

Conveniently, the application for a license to manufacture for sale or for distribution for medical devices of any class can be found, completed, and submitted on the Ministry of Health and Family Welfare's **online portal**.⁷ The Central Drugs Standard Control Organization (CDSCO) has launched online service for grant of import, manufacture, clinical investigation, sale and distribution licences of medical devices and diagnostics in Sugam portal. All applications for import, manufacture, sale or distribution and clinical investigation, whether to be examined by the Drug Controller General of India (DCGI) or State Licensing Authority, will have to be made through a single online portal of the CDSCO i.e. Sugam portal. The applicants seeking renewal of licences are also required to submit application online.

Quality Management Systems

QMS regulates the design and development, packaging and servicing of medical devices. The Rules have introduced a framework wherein

certain "Notified Bodies" would undertake verification and assessment of the quality management system. Notified Bodies will audit manufacturing sites and products to ensure conformity to standards. **In 2020, approved medical devices must bear unique identifiers.** Starting on January 1st, 2022, medical devices that are approved for import, sale, or distribution in India must bear two different types of unique identifiers:⁸

1. The Device Identifier: It is a global trade item number
2. The Production Identifier: It is the device's serial number, lot/batch number, software version, and/or manufacturing and/or expiration date.

Medical devices novel to the Indian market are subject to special regulations.

An application for grant of permission and clinical investigation is required for any medical device (except for that in Class A which does not have its predicate device on India's medical device market before it is sold or distributed in India.

If the device has been approved by the regulatory authority in the U.S., the U.K., Australia, Canada, or Japan, the device has been marketed in that country for at least 2 years, and the data of safety, performance, and Pharmacovigilance of the device complies with the standards of the Central Licensing Authority, additional clinical investigation may not be required for that device.⁹

Orthopedic implants

An orthopaedic implant is a medical device manufactured to replace a missing joint or bone or to support a damaged bone¹⁰. Classified under class – C & D of the medical devices because of their moderate to high risk to the human body in Indian system. In EU or US these are classified under Class IIb and Class ii, Class iii respectively. Previously **Revised Schedule M III** (Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Medical Devices) was followed but there are issues regarding developing facilities, where, unnecessary arrangement of area were insisted by regulatory authorities, Lack of knowledge about Medical Devices, Lack of implementation of Rules. This in turn results into increase in cost of medical devices. So, after implementation of new rules, the medical device industries are presuming that there will be specificity in design of product because, now

The manufacturing organization shall determine and provide the resources needed

(a) To implement the quality management system and to maintain its effectiveness, and

(b) To meet regulatory and customer requirements.

Table: 1 Environmental requirement for medical devices and in-vitro diagnostic medical devices¹⁰

Name of Device	Type of Operation	ISO Class (At rest)
Cardiac stent/Drug Eluting Stent	Primary Packing and Crimping	5
	Washing, Ultrasonic cleaning & Drug Coating	7
	Assembly, Wrapping and Packaging	8
	Assembly, Wrapping and Packaging	9
Heart Valves	Valve Packing	5
	Ultrasonic Cleaning and Visual Inspection	7
	Frame and Disc Assembly	7
Orthopaedic Implants	Cleaning and packaging (to be sterilized in factory premises)	7
	Cleaning and packaging (Non Sterile to be sterilized in Hospital)	8
	Cutting, lathing, and Polishing	9
In-vitro diagnostic medical devices (Kit/Reagents)	Dry, Liquid Reagent Preparation	Well Lighted and Ventilated controlled temperature & humidity as per process or product requirement
	Coating of sheets etc. Assembly and primary packing	
	Filling	Well Lighted and Ventilated controlled temperature and humidity as per process or product requirement. Provision of Laminar hood if

		required, Clean Room class 8 or class 9 as per product/process requirement
	Secondary Packing	Well Lighted and Ventilated controlled temperature if required
	Storage	As per recommended storage condition of the product

Establishment of Medical Device Testing Labs

In order to ensure safety and efficacy of medical devices marketed in the country, the Union government plans to set up two dedicated medical device testing laboratories in the country at Vadodara in Gujarat and Noida in Uttar Pradesh, based on a survey conducted by National Health Systems Resource Centre (NHSRC). The medical device testing lab in Gujarat would be the first and the only dedicated biomaterials and implants testing lab in the country. The lab at Noida will be set up primarily to test electrical and electronic medical devices in the country. Such type of testing labs will allow manufacturers to overcome deficiencies in their products and improve product value in the market which is a neglected aspect until now.¹¹

CONCLUSION

From this review I conclude that till, 2017 there was no such strict regulations for Medical devices manufacturing, import and sale. From starting 1st January 2018, new regulations implemented by Indian Ministry of Health and Family Welfare. According to these rules, Test licenses will remain valid for three years; before, it is valid for one-year only. Now, Device manufacturing sites in India must undergo audits by Notified Bodies in order to obtain manufacturing license. In 2020, approved medical devices must bear unique identifiers. Starting on January 1st, 2022, medical devices that are approved for import, sale, or distribution in India must bear two different types of unique identifiers. In order to ensure safety and efficacy Government setup testing laboratories in the country to overcome deficiencies in the Medical Device products.

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